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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,641	06/25/2003	John M. Heasley	6656320/24780	2762

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JOHN M. HEASLEY  
1614 COVER SHEET  
IOWA CITY, IA 52240

EXAMINER
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BUMGARNER, MELBA N

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 03/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/603,641	<b>Applicant(s)</b> HEASLEY, JOHN M.	
	<b>Examiner</b> Melba Bumgarner	<b>Art Unit</b> 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/10/04, 9/24/03</u> . | 6) <input type="checkbox"/> Other: ____  |

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to because figure on page 2 is not numbered. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether gingival retraction material is intended to be positively

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claimed as it is further limited in the claims. Claims 8 and 9 contain improper Markush expressions. Several preambles are improper, such as in claims 9 and 24. There are numerous instances of lack of antecedent basis in the claims, such as the recitation of “the shells” in claim 10. It is unclear what structure is claimed in claim 30.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-12, 17-25, and 27-30 are rejected as understood, under 35 U.S.C. 102(b) as being anticipated by Spinello (4,531,914). Spinello discloses gingival retraction devices comprising a structural backing component 15 which transmits simultaneous circumferential vertical forces to insert gingival retraction material into the gingival crevice. The structural backing component 37 is of malleable and flexible composition. The retraction devices include a retraction material 13 attached or applied to the structural backing component. The retraction devices are of a form of shells (column 5 line 18). The structural backing component comprises malleable or flexible plastic (column 7 line 45), which is filled with retraction material of putty (column 5 line 26). The retraction material contain vasoconstrictive agents (column 5 line 9). Spinello discloses a method of adjusting adapting the malleable gingival retraction devices wherein the size, form and contours of the devices are fit to be inserted precisely in the gingival crevice adapted by pressure on the device (column 7 line 54, column 8 line 8). The retraction material comprises hydrogel of polymeric material (column 3 line 13). The retraction devices

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further comprises impression material (column 10 line 10). Spinello shows gingival retraction tape (column 7 line 47).

6. Claims 1-10, 12, 14, 17-20, and 25 are rejected as understood, under 35 U.S.C. 102(b) as being anticipated by Lytton (3,390,458). Lytton discloses gingival retraction devices comprising a structural backing component 1 which transmits simultaneous circumferential vertical forces to insert gingival retraction material into the gingival crevice, the component is of malleable and flexible composition. The retraction devices include a retraction material 4 attached or applied to the structural backing component. The retraction devices are of a form of shells or domes (figures 2, 11). The structural backing component comprises malleable or flexible plastic, which is filled with retraction material of putty (column 3 line 40). Lytton discloses a method of adjusting adapting the malleable gingival retraction devices wherein the size, form and contours of the devices are fit to be inserted precisely in the gingival crevice (column 4 line 24) adapted by pressure on the device.

7. Claims 1-10, 12, 14-20, and 25 are rejected as understood, under 35 U.S.C. 102(b) as being anticipated by Cohen (3,548,500). Cohen discloses gingival retraction devices comprising a structural backing component 10, which transmits simultaneous circumferential vertical forces to insert gingival retraction material into the gingival crevice, the component is of malleable and flexible composition. The retraction devices include a retraction material 4 attached or applied to the structural backing component. The retraction devices are of a form of cylindrical bands. The structural backing component comprises malleable metal (column 2 line 64) or flexible plastic (column 3 line 43), which is filled with retraction material of putty 22. Cohen discloses a method of adjusting adapting the malleable gingival retraction devices wherein the size, form

and contours of the devices are altered by a clinician, which includes increasing the circumferential opening (column 3 line 19), crimping the devices with a tool (column 3 line 39), or trimming with a tool (column 3 line 24).

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 13 is rejected as understood, under 35 U.S.C. 103(a) as being unpatentable over Cohen. Cohen discloses a method that shows the limitations as described above; however, Cohen does not show increasing the circumferential diameter of the device by forcing it over the plastic frustoconical dies. It would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust and adapt the device of the expandable band of Cohen by forcing over the tooth or die.

10. Claim 26 is rejected as understood, under 35 U.S.C. 103(a) as being unpatentable over Cohen in view of Spinello. Cohen discloses a method that shows the limitations as described above; however, Cohen does not show injecting material into the device with a syringe. It would have been obvious to one of ordinary skill in the art to inject the impression material through the opening with a syringe as such syringe is known in the art to dispense dental impression or flowable material as taught by Spinello 51.

*Conclusion*

11. Any inquiry concerning this communication from the examiner should be directed to Melba Bumgarner whose telephone number is 571-272-4709. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at 571-272-4720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Melba Bumgarner  
Primary Examiner